Amendment to the Claims

The following is a complete listing of all claims of the application.

Claims 1 - 12 Canceled.

Claim 13. (Currently amended) A mycotoxin adsorbent comprising

an organically modified (organophilic) layered silicate comprising a quaternary onium compound, wherein said quaternary onium compound includes at least a C_{10} to C_{22} alkyl group and an aromatic substituent, and wherein about 2 to about 30 percent of exchangeable cations of the layer silicate are exchanged with quaternary onium compounds.

Claim 14. (Currently amended) A mycotoxin adsorbent comprising

a mixture of a layered silicate, which has not been organically modified, and a layered silicate, which has been organically modified to at least about 75 percent of its total cation exchange capacity (CEC), wherein the originally modified layered silicate comprises from about 0.1 to about 50 percent of the mixture.

Claim 15. (Previously presented) The mycotoxin adsorbent of Claim 14 wherein the organically modified layered silicate comprises a quaternary onium compound including at least a C_{10} to C_{22} alkyl group and at least one aromatic substituent.

Claim 16. (Previously presented) The mycotoxin adsorbent of Claim 13 wherein the C_{10} to C_{22} alkyl group comprises a C_{14} to C_{18} alkyl group.

Claim 17. (Previously presented) The mycotoxin adsorbent of Claim 15 wherein the C_{10} to C_{22} alkyl group comprises a C_{14} to C_{18} alkyl group.

Claim 18. (Previously presented) The mycotoxin adsorbent of Claim 13 wherein the quaternary onium compound is selected from a group consisting of stearylbenzyldimethylammonium chloride, coconut alkyldimethylbenzylammonium chloride, dimethyllaurylbenzylammonium chloride, distearylmethylbenzylammonium chloride or quaternized tallow imidazolinium methosulfate is used as quaternary onium compound.

Claim 19. (Previously presented) The mycotoxin adsorbent of Claim 15 wherein the quaternary onium compound is selected from a group consisting of stearylbenzyldimethylammonium chloride, coconut alkyldimethylbenzylammonium chloride, dimethyllaurylbenzylammonium chloride, distearylmethylbenzylammonium chloride or quaternized tallow imidazolinium methosulfate is used as quaternary onium compound.

Claim 20. (Previously presented) The mycotoxin adsorbent of Claim 13 wherein the organically modified layered silicate comprises a smectite clay mineral.

Claim 21. (Previously presented) The mycotoxin adsorbent of Claim 14 wherein the organically modified layered silicate comprises a smectite clay mineral.

Claim 22. (Previously presented) The mycotoxin adsorbent of Claim 13 wherein the organically modified layered silicate comprises a montmorillonite-containing clay.

Claim 23. (Previously presented) The mycotoxin adsorbent of Claim 14 wherein the organically modified layered silicate comprises a montmorillonite-containing clay.

Claim 24. (Previously presented) The mycotoxin adsorbent of Claim 13 wherein the organically modified layered silicate comprises a bentonite clay.

Claim 25. (Previously presented) The mycotoxin adsorbent of Claim 14 wherein the organically modified layered silicate comprises a bentonite clay.

Claim 26. (Currently amended) The mycotoxin adsorbent of Claim ~~14~~ 13 wherein no more than 75 percent of exchangeable cations of the layered silicate which has been organically modified are exchanged with a quaternary onium compound.

Claim 27. (Canceled)

Claim 28. (Currently amended) The mycotoxin adsorbent of Claim ~~14~~ 13 wherein about 2 to about 15 percent of the exchangeable cations of the layered silicate which has been organically modified are exchanged with quaternary onium compounds.

Claim 29. (Currently amended) The mycotoxin adsorbent of Claim ~~14~~ 13 wherein about 2 to about 10 percent of the exchangeable cations of the layered silicate which has been organically modified are exchanged with quaternary onium compounds.

Claim 30. (Currently amended) The mycotoxin adsorbent of Claim 14 wherein the organically modified layered silicate comprises from about ~~0.1~~ 0.5 to about ~~50~~ 30 weight percent of the adsorbent.

Claim 31. (Previously presented) The mycotoxin adsorbent of Claim 14 wherein the organically modified layered silicate comprises from about 0.5 to about 20 weight percent of the adsorbent.

Claim 32. (Previously presented) The mycotoxin adsorbent of Claim 14 wherein the organically modified layered silicate comprises from about 0.5 to about 10 weight percent of the adsorbent.

Claim 33. (Currently amended) A mycotoxin adsorbent comprising

an organically modified (organophilic) layered silicate comprising a quaternary onium compound, wherein said quaternary onium compound includes at least a C_{14} to C_{18} alkyl group and an aromatic substituent, and wherein about 2 to about 30 percent of exchangeable cations of the layer silicate are exchanged with quaternary onium compounds.

34. (Currently amended) A mycotoxin adsorbent comprising

a mixture of a layered silicate which has not been organically modified and a layered silicate which has been organically modified to at least about 75 percent of its total cation exchange capacity (CED) wherein the organically modified layered silicate includes at least a C_{14} to C_{18} alkyl group and at least one aromatic substituent, wherein the originally modified layered silicate comprises from about 0.1 to about 50 percent of the mixture.

Claim 35. (Previously presented) A feed additive comprising a mycotoxin adsorbent which comprises an organically modified

(organophilic) layered silicate comprising a quaternary onium compound, wherein said quaternary onium compound includes at least a C_{10} to C_{22} alkyl group and an aromatic substituent.

Claim 36. (Previously presented) A feed additive comprising a mycotoxin adsorbent, wherein the mycotoxin adsorbent comprises a mixture of a layered silicate which has not been organically modified and a layered silicate which has been organically modified to at least about 75 percent of its total cation exchange capacity (CEC).

Claim 37. (Previously presented) A premix for production of a feed additive comprising the mycotoxin adsorbent of Claim 13 containing more than 50 percent organically modified layered silicate.

Claim 38. (Previously presented) A process for the adsorption of mycotoxins in feeds comprising treating the feeds with the mycotoxin adsorbent of Claim 13.

Claim 39. (Previously presented) A process for the adsorption of mycotoxins in feeds comprising treating feeds with the mycotoxin adsorbent of Claim 14.

The applicants have amended independent Claim 13 to assert that the percentage of exchangeable cations of the layered silicate that is present in the mycotoxin adsorbent and which are exchanged with quaternary onium compounds is from about 2 to about 30 percent. Basis for this amendment is contained on page 5, lines 10 - 12 and in canceled Claim 27.

The applicants have also amended Claim 14 to assert that the mixture of organically modified and non-organically modified layered silicates comprises from about 0.1 to 50 percent of organically modified layered silicates. Basis for this amendment is contained on page 7, lines 4 - 5.

The dependency of Claims 26, 28 and 29 has been amended to depend on Claim 13 rather than Claim 14 to correct the dependency of those claims.

Claim 30 has been amended to change the percentage of the organically modified layered silicate that may be present in the mixture. This amendment was necessary because of the amendment to Claim 14. Support for this amendment is contained on page 7, lines 22 - 24.

Independent Claim 33 has also been amended in the same manner as Claim 13 and independent Claim 34 has been amended in the same manner as Claim 14.

No new subject matter is introduced by any of these amendments.

Discussion

The application as filed included Claims 13 - 39. The USPTO rejected Claim 13 - 34 as being anticipated by Lemke, et. al. The applicants respectfully traverse this rejection based on the amendments to the various claims. Notwithstanding, Claims 35 - 39 have been allowed, for which the applicants wish to thank the Examiner.

In one embodiment (Claims 13, 33 and dependent claims depending thereon), the applicants have discovered an adsorbent material for mycotoxins, which contains layered silicates modified with quaternary onium compounds containing at least one C_{10}-C_{22} alkyl group and at least one aromatic substituent, wherein from about 2 to about 30 percent of the exchangeable cations of the layered silicates are exchange with quaternary onium compounds. (Claim 13, as amended) A second embodiment of this invention is a mycotoxin adsorbent comprising a mixture of organically modified layered silicates and non-organically modified silicates, wherein the organically modified layered silicates comprise from about 0.1 to about 50 percent of that mixture. (Claims 14, 34 and dependent claims depending thereon.) The applicants respectfully assert that these claims, as amended, are not disclosed by the prior art and are thus allowable.

The USPTO rejected Claims 13 - 34 based on Lemke, et. al. This reference discloses a composition which is designed to adsorb

zearalenone (ZEN) using an organophilic montmorillonite clay. The montmorillonite clay that is disclosed in Lemke, et. al. has a cation exchange capacity (CEC) of about 90 mol/kg of clay. (Page 3797, Col. 2, last line.) Lemke, et. al. teach that the organophilic clay composition that adsorbs best should be exchanged to the extent of 1.5 times its CEC.

> The 1.5 CEC CP-exchanged clay exhibited the best binding of ZEN as measured by *K* values and, further studies were based on this exchanged level of clay alone. (Lemke, et. al., page 3792, col. 2, lines 8 - 11.)

Lemke, et. al. further assert that only these higher cation exchanged materials work effectively to adsorb ZEN.

> In keeping with previous evidence, it was found that the greater the hydrophobicity of the clay, that is, the amount of CP exchanged by the clay, the higher the affinity of the binding ZEN. (Lemke, et. al., page 3793, col. 2. lines 29 - 32.)

In particular, Figure 3 of Lemke, et. al. on page 3794 shows a significant improvement in the performance of organically exchanged clay which has been cation exchanged to more than about 75% of capacity. Note particularly, that there is virtually no adsorption of ZEN when the percentage of the layered silicate that has been cation exchanged is 25 percent.

The USPTO asserts that Lemke, et. al. only teach the use of organically exchanged clays exchanged at least 75 percent, by stating that "Lemke, et. al. teach acidic montmorillonite clays

modified via exchange with ammonium and pyridinium organic cations, exchanged to more than about 75 percent." (Office Action, page 2, paragraph 1.) Thus, all parties including the USPTO, agree that Lemke, et. al. teach that to produce an effective organically modified clay material for the adsorption of ZEN, the clay material must be exchanged to at least 75 percent of the CEC of the clay material.

In contrast, the applicants have surprisingly discovered that very good adsorption performance can be achieved for the adsorption of both aflatoxin and non-aflatoxin-type mycotoxins when the cation exchange of the clay material is maintained well below 75 percent of its CEC. In particular, on page 5, paragraph 2 of the application, the applicants state that,

> ...even when the exchange rate is a low as 2 to 30%, preferably, 2 to 15%, especially, 2 to 10% of the CEC, the adsorbents according to the invention exhibit significant adsorption of mycotoxins.

This percentage of cation exchange is far below what is taught or suggested by Lemke, et. al. (Note particularly that there is no disclosure in Lemke, et. al. of and exchanged clay with an exchange percentage in the range of 2 to 15 % (Claim 28) or in the range of 2 - 10 percent (Claim 29).) For this reason, the applicants assert that independent Claims 13 and 33 and the dependent claims which depend thereon, are not taught by Lemke, et. al.

Although the teaching of Lemke, et. al. is relevant for all

that it discloses, it is clear that Lemke, et. al. can be cited against the claims of this application only if the scope of the claims of the application are suggested to one having ordinary skill in the art after reading Lemke, et. al. Merck and Co. vs. BioCraft Laboratories, 874 Fed.2d 804, 10 USPQ 1843 (Fed. Cir.), cert. denied 493 U.S. 975, (1989); MPEP 2123. A person skilled in the art reviewing Lemke, et. al. would be taught to exchange clay with organic onium compounds to an exchange rate of at least 75 percent. Further, a person skilled in the art would be taught by Lemke, et. al. that the use of an organically modified layered silicate, wherein only 2 to about 30 percent of the exchangeable cations of the layered silicate are exchanged, as now claimed in Claim 13, or the lower percentages claimed in Claims 28 (2 to 15%) or 29 (2 to 10%) would not produce a material useful for the adsorption of mycotoxins.

Independent of the patentability of Claims 13, 33 and the dependent claims depending thereon is the patentability of Claim 14, 34 and the dependent claims which depend thereon. These claims claim a composition different from what is claimed in Claim 13. They specifically require a mixture of layered silicates, a portion of which have been organically modified and a portion of which have not been organically modified. The organically modified layered silicates need only comprise from about 0.1 to about 50 percent of the overall mixture. Lemke, et. al. fail to teach that non-

organically modified layered silicates should ever be mixed with organically modified layered silicates for the removal of ZEN. In fact, Lemke, et. al. state that non-exchanged clays "showed no significant interaction with ZEN. (Lemke, et. al. p. 3793, col. 1, last paragraph). Rather, Lemke, et. al. teach that the layered silicate should be exchanged with quaternary onium compound to a CEC of 150 percent. Lemke, et. al. therefore requires that only organically modified layered silicates should be used. (See Lemke, et. al., page 392, first full paragraph of the second col.)

In contrast, the applicants have discovered that the use of non-organically modified layered silicates with organically modified silicates produces a superior product. One theoretical mechanism which supports this surprising discovery is discussed in the second paragraph on page seven of the application. It is believed that the hydrophobic surface of the organically modified layered silicate and the surface of the unmodified layered silicate interact resulting in effective adsorption and low desorption of mycotoxins. It is assumed that the aflatoxins primarily bind to the unmodified layered silicate in a mixture of organically modified and unmodified layered silicate, so that the surface of the organically modified layered silicate is available for the non-aflatoxins that can not be adsorbed on the unmodified layered silicate. Due to this synergistic interaction, good absorption performance with respect to non-aflatoxins is guaranteed at

relatively high aflatoxin concentrations.

Thus, the applicants have surprisingly discovered that it is necessary to blend both modified and non-modified layered silicates to achieve this surprisingly result. Lemke, et. al. fail to recognize or anticipate this phenomena and assert that improved performance is achieved only with layered silicates that have been exchanged at the highest possible level of cation exchange.

There is, thus no disclosure in Lemke, et. al. of blending non-cation exchanged layered silicates with cation exchanged layered silicate, as is claimed in Claim 14, 34 and dependent claims which depend thereon. Accordingly, the applicants believe that these claims are not taught by Lemke, et. al. , and are allowable over Lemke, et. al.

In addition, it is also interesting to note, that claims containing almost exactly the same coverage were allowed by the European Patent Office over this exact reference in PCT/EP99/10088. Thus, the European Patent Office has recognized that Lemke, et. al. do not disclose the subject matter of the claims of the application.

CONCLUSION

The applicants respectfully assert that all claims of the application, as amended, are now in condition for allowance and request a further review of the amended claims. If there are any questions concerning this Amendment, please contact applicants' counsel.

Respectfully submitted,

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CERTIFICATE OF SERVICE

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Dated: May 7, 2004 Holly Hart

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